REMARKS

I. Introduction

By the present Amendment, claims 1, 3, 5, and 7-10 have been amended, and claim 2 cancelled. Accordingly, claims 1 and 3-11 remain pending in the application. Claims 1, 3, and 8-10 are independent.

II. Office Action Summary

In the Office Action of July 12, 2007, claim 9 was rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 6,180,372 issued to Franzen. Claims 1, 2, 7, and 8 were rejected under 35 USC §103(a) as being unpatentable over Franzen in view of U.S. Patent Application No. 2006/0011478 to Fouillet et al. ("Fouillet"). Claims 3-6, 10, and 11 were rejected under 35 USC §103(a) as being unpatentable over Franzen in view of Fouillet and further in view of U.S. Patent Application No. 2005/0221373 to Enzelberger et al. ("Enzelberger"). These rejections are respectfully traversed.

III. Rejections under 35 USC §102

Claim 9 was rejected under 35 USC §102(b) as being anticipated by Franzen. Regarding this rejection, the Office Action alleges that Franzen discloses a nucleic acid amplifying method that comprises a branch step for branching a reaction fluid containing a sample of nucleic agent and reagent, a flow passage that includes a branch portion for creating a plurality of parallel fluid passages. The Office Action further indicates that the branched reaction fluid parts are repeatedly heated and cooled at a plurality of different temperatures.

By the present Amendment, independent claim 9 has been amended to better define the claimed invention and identify features that are not disclosed in the art of record. As amended, independent claim 9 defines a nucleic acid amplifying method that comprises:

> a branch step for branching a reaction fluid containing a sample containing a nucleic acid and a reagent being mixed with the sample;
>
> a repeated heating and cooling step for repeatedly heating and cooling the branched reaction fluid parts between a first set temperature and a second set temperature; and
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> a junction step for joining the plurality of branched reaction fluid parts that have been repeatedly heated and cooled;
>
> wherein the first set temperature is 95°C, and the second set temperature is provided as a range of 55°C to 62°C at intervals of 1°C.

According to the method of independent claim 9, a branch step is provided for branching a reaction fluid that contains a sample of a nucleic acid and a reagent being mixed with the sample. The reaction fluid is repeatedly subjected to a heating and cooling between a first set temperature and a second set temperature. The branched reaction fluid parts that were subjected to the repeated heating and cooling are subsequently joined together. According to independent claim 9, the first set temperature is 95°C, and the second set temperature is provided as a temperature range that varies from 55°C to 62°C at intervals of 1°C.

The Office Action alleges that Franzen discloses all the features recited in independent claim 9. Applicants' review of Franzen, however, has failed to reveal any disclosure for the features that have been newly added to independent claim 9. Franzen discloses a method and device for fast and selective replication of DNA through biomaterial using polymerase chain reaction working in individual duplication

thermal cycles. Franzen discloses the use of multiple temperature settings, as suggested in the Office Action. However, the manner in which the heating and cooling variations are conducted differs greatly from that of the instant invention. More particularly, as recited in independent claim 9, the second set temperature is in the form of a temperature range. The temperature range extends from 55°C to 62°C. Furthermore, the temperature range is simultaneously applied as the second set temperature. As discussed in the Specification, multiple heaters can be provided to control the temperature at which the fluid is processed. See page 19, lines 1-17. When providing the second temperature set, the individual heating elements are controlled such that the area where the second set temperature is being applied substantially forms a temperature gradient ranging from of 55°C to 62°C. Further, the individual heating elements are controlled such that the temperature gradient changes at 1°C increments. Franzen fails to provide any disclosure for such a temperature range. More particularly, the cited reference fails to disclose features recited in independent claim 9, such as:

> wherein the first set temperature is 95°C, and the second set temperature is provided as a range of 55°C to 62°C at intervals of 1°C.

It is therefore respectfully submitted that independent claim 9 is allowable over the art of record.

IV. Rejections under 35 USC §103

Claims 1, 2, 7, and 8 were rejected under 35 USC §103(a) as being unpatentable over Franzen in view of Fouillet. Regarding this rejection, the Office Action alleges that Franzen discloses a nucleic acid amplifying apparatus that includes a flow passage through which a reaction fluid containing nucleic acid and a

reagent flow. The flow passage is indicated as including a flow passage branch portion at which the flow passage branches into a plurality of flow passages, and a junction portion at which the plurality of flow passages are joined. The Office Action admits that Franzen fails to expressly disclose a plurality of set temperature zones that is provided by a first and second heating mechanism. Fouillet is relied upon for disclosing a thermal cycling device for amplifying nucleic acid samples, wherein fluids are repeatedly passed through a plurality of zones heated by different mechanisms. Applicants respectfully disagree.

As amended, independent claim 1 defines a nucleic acid amplifying apparatus that comprises:

> a flow passage, through which a reaction fluid containing a sample containing a nucleic acid and a reagent flows, said flow passage including,
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> a flow passage branch portion, at which the flow passage branches into a plurality of branch flow passages,
>
> a junction portion, at which the plurality of branch flow passages join, and
>
> a joined flow passage, through which the reaction fluid as joined is conducted;
>
> a first heating mechanism having a plurality of first set temperature zones of 95°C provided on the branch flow passages; and
>
> a second heating mechanism provided on the branch flow passages, said second heating mechanism including a plurality of second set temperature zones ranging from 55°C to 62°C at intervals of 1°C;
>
> wherein the branch flow passages are arranged so as to repeatedly pass through the first and second set temperature zones.

The nucleic acid amplifying apparatus of independent claim 1 includes a flow passage through which a reaction fluid containing nucleic acid and a reagent flows. The flow passage includes a flow passage branch portion, a junction portion, and a

joined flow passage. The flow passage branches into a plurality of flow branch passages at the flow passage branch portion, and are rejoined at the junction portion. The joined flow passage is used to transport the reaction fluid as it is being joined at the junction portion. According to independent claim 1, the apparatus includes a first heating mechanism having a plurality of first set temperature zones provided on the branch flow passages. The first heating mechanism is controlled to provide a temperature of 95°C. Furthermore, a second heating mechanism is provided on the branch flow passages that includes a plurality of second set temperature zones. The second set temperature zones have a range of 55°C to 62°C. Additionally, each temperature zone is incremented from the previous zone at an interval of 1°C.

The Office Action alleges that Fouillet discloses a plurality of temperature zones. Applicants respectfully submit, however, that the temperature zones disclosed in Fouillet differ from those of the instant invention. For example, Fouillet indicates that micro-channels can be provided so that the samples can be continually circulated for purposes of controlling the temperature of different zones. As illustrated in Fig. 12, however, the micro-channels are arranged such that the temperature zones occur successively. Importantly, Fouillet appears to teach away from this type of configuration by stating that "a major drawback of this arrangement is that it imposes limits which are prohibitive for miniaturization, flexibility and throughput (in the sense that it is not feasible to have a large number of parallel chennels)." See paragraph [0206]. Consequently, even if the arrangement illustrated in Fouillet could be interpreted as being the same as that of the claimed invention (which it is not), one of ordinary skill in the art would not have been motivated to combine this arrangement with that of Franzen because it is indicated

as being inferior. The cited references simply fail to provide any disclosure or suggestion for features recited in independent claim 1, such as:

> a first heating mechanism having a plurality of first set temperature zones of 95°C provided on the branch flow passages; and
>
> a second heating mechanism provided on the branch flow passages, said second heating mechanism including a plurality of second set temperature zones ranging from 55°C to 62°C at intervals of 1°C;
>
> wherein the branch flow passages are arranged so as to repeatedly pass through the first and second set temperature zones.

It is therefore respectfully submitted that independent claim 1 is allowable over the art of record.

Claim 7 depends from independent claim 1, and is therefore believed allowable for at least the reasons set forth above with respect to independent claim 1. In addition, this claim introduces novel elements that independently render it patentable over the art of record.

Independent claim 8 defines a chemical analysis apparatus that comprises:

> a flow passage, through which a reaction fluid containing a sample containing a nucleic acid and a reagent being mixed with the sample flows, said flow passage including,
>
> a flow passage branch portion, at which the flow passage branches into a plurality of branch flow passages,
>
> a junction portion, at which the plurality of branch flow passages join together,
>
> a joined flow passage, through which the reaction fluid as joined is conducted, and
>
> a detection part that detects the nucleic acid in the reaction fluid conducted to the joined flow passage; and
>
> a first heating mechanism having a plurality of first set temperature zones of 95°C provided on the branch flow passages; and

> a second heating mechanism provided on the branch flow passages, said second heating mechanism including a plurality of second set temperature zones ranging from 55°C to 62°C at intervals of 1°C;
>
> wherein the heating mechanism is formed such that the branch flow passages repeatedly pass through the plurality of set temperature zones.

The chemical analysis apparatus of independent claim 8 includes various features that are somewhat similar to those recited in independent claim 1. For example, the second set temperature zone is in the form of a range of 55°C to 62°C that is incremented at intervals of 1°C. As previously discussed, the combination of references fails to provide any disclosure or suggestion for such a feature. Additionally, Fouillet appears to teach away from the arrangement identified by the Office Action, and consequently appears to be improperly combined with Franzen. It is therefore respectfully submitted that independent claim 8 is allowable over the art of record.

Claims 3-6, 10, and 11 were rejected under 35 USC §103(a) as being unpatentable over Franzen over Fouillet and further in view of Enzelberger. Regarding this rejection, the Office Action further admits that Franzen and Fouillet do not expressly disclose the use of a second branch portion and second flow passages. Enzelberger is relied upon for disclosing these particular features. Applicants respectfully disagree.

By the present Amendment, independent claim 3 has been amended to recite, in part:

> a first heating mechanism having a plurality of first set temperature zones of 95°C provided on the first branch flow passages; and
>
> a second heating mechanism provided on the second branch flow passages, said second heating mechanism including a

> plurality of second set temperature zones ranging from 55°C to 62°C at intervals of 1°C.

As previously discussed, these particular features are not shown or suggested by the combination of Franzen and Fouillet. Furthermore, the features that are lacking in Franzen and Fouillet do not appear to be disclosed or suggested by Enzelberger. Consequently, the combination of these three references still fails to disclose or suggest the various features recited in independent claim 3.

It is therefore respectfully submitted that independent claim 3 is allowable over the art of record.

Claims 4-6 depend from independent claim 3, and are therefore believed allowable for at least the reasons set forth above with respect to independent claim 3. In addition, these claims each introduce novel elements that independently render them patentable over the art of record.

By the present Amendment, independent claim 10 has been amended to define a nucleic acid amplifying method that comprises in part:

> a first branch step for branching a reaction fluid containing a sample containing a nucleic acid and a reagent being mixed with the sample;
>
> a first repeated heating and cooling step for repeatedly heating and cooling the branched reaction fluid parts between a first set temperature and a second set temperature, wherein the first set temperature is 95°C, and the second set temperature is provided as a range of 55°C to 62°C at intervals of 1°C,

As previously discussed, these particular features are now shown or suggested by the art of record taken either individually or in combination.

It is therefore respectfully submitted that independent claim 10 is allowable over the art of record.

Claim 11 depends from independent claim 10, and is therefore believed allowable for at least the reasons set forth above with respect to independent claim 10. In addition, this claim introduces novel elements that independently render it patentable over the art of record.

V. Conclusion

For the reasons stated above, it is respectfully submitted that all of the pending claims are now in condition for allowance. Therefore, the issuance of a Notice of Allowance is believed in order, and courteously solicited.

If the Examiner believes that there are any matters which can be resolved by way of either a personal or telephone interview, the Examiner is invited to contact Applicants' undersigned attorney at the number indicated below.

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AUTHORIZATION

Applicants request any shortage or excess in fees in connection with the filing of this paper, including extension of time fees, and for which no other form of payment is offered, be charged or credited to Deposit Account No. 01-2135 (Case: 500.43725X00).

Respectfully submitted,
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